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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,566	01/23/2004	Richard Franklin	20342/1202529-US1	3220

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,566	FRANKLIN, RICHARD	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, drawn to a method for the treatment or prevention of thrombocythemia, classified in class 514, subclass 266.220.

II. Claim 37, drawn to a method of reducing the platelet count in a patient's bloodstream, classified in class 514, subclass 266.220.

III. Claim 38, drawn to a method for reducing the side effects associated with the oral administration of anagrelide, classified in class 514, subclass 266.220.

IV. Claims 39-40, drawn to a composition comprising anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide and at least one skin penetration enhancer, classified in class 514, subclass 266.220.

V. Claims 41-42, drawn to a composition comprising anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide and at least one adhesive, classified in class 514, subclass 266.220.

VI. Claims 43-48, drawn to a medical device for the transdermal administration to a patient of anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide wherein the device is comprised of a skin permeable reservoir means containing a form of anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt form of anagrelide, classified in class 514, subclass 266.220.

VII. Claim 49, drawn to a medical device for the transdermal administration to a patient of anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide that is comprised of a backing layer, a release liner, and at least one anagrelide composition layer situated in between and one adhesive, classified in class 514, subclass 266.220.

Inventions I, II, III, IV, and V are related as product (IV and V) and process of use (I, II, and III). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products in Inventions IV and V can be used to treat myeloproliferative diseases and conditions, such as severe hypersensitivity pneumonitis.

Inventions I, II, III, VI, and VII are related as process (I, II, and III) and apparatus (VI and VII) for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the devices in Inventions VI and VII may be utilized broadly for the administration of locally acting drugs such as antibacterials, anti-fungals, anti-inflammatories, antiporasitics, antiperspirants and deodorants, and the like (See U.S. Patent No. 3731683).

Inventions I, II and III are related one to another in that each involves the administration of anagrelide. Invention I utilizes the administration of anagrelide to treat or prevent thrombocythemia, which is an especially abnormal increase in the number of blood platelets

while Invention II utilizes the administration of the same active ingredient to reduce blood platelet count, which can be the cause of a number of diseases and conditions in addition to thrombocythemia, for example certain types of leukemia, polycythemia vera, and sickle cell anemia and Invention III utilizes a method of administering anagrelide that enables the active ingredient's failure to metabolize in certain areas of the body so as to minimize the ingredient's common side effects.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specie Election

This application contains claims directed to the following patentably distinct species, should Applicant elect Invention I, and a choice of one from each of the following 2 species is required to be elected for examination:

1) Mode of composition administration – Implants, sublingual, pregastric absorption, pessary, suppository, transdermal means (subspecie election required, *infra*), nasal spray, inhaled absorption or topical means.

2) Associated diseases or conditions – essential thrombocythemia, chronic myologenous leukemia, polycythemia vera, agnogenic myeloid metaplasia, and sickle cell anemia.

The species are independent or distinct because, in the case of modes of composition administration, because of their different means of penetrating the body and resultant variable

functionality, for example through the vagina (pessary) which would, in addition to treating diseases and conditions associated with the current invention, also may be utilized to treat other unrelated conditions such as yeast infections and through the anus (suppository) which would, in addition to treating diseases and conditions associated with the current invention, also be utilized to treat conditions such as constipation and/or diarrhea, a search for one mode of composition administration would not necessarily yield search results for another. In the case of diseases and conditions associated with thrombocythemia, because the diseases marked by variable symptoms in variable populations and therefore, often require variable treatments, a search for one would not necessarily yield results for another. For example, sickle cell anemia is marked by sickle-shaped red blood cells, occurring almost exclusively in Black people of Africa or of African descent, and characterized by episodic pain in the joints, fever, leg ulcers, and jaundice while polycythemia vera is marked by an increase in blood volume and red blood cells, bone marrow hyperplasia, redness or cyanosis of the skin, and enlargment of the spleen.

The applicant is required under 35 U.S.C. 121 to elect a single disclosed species within each group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In addition to the above election requirement under 35 U.S.C. 121, if Applicant elects transdermal administration, Applicant must elect a subspecies penetration enhancer that is either linalool, carvacrol, thymol, citral, menthol or t-anethole. As noted with the species above, so too, a search for one subspecies will not necessarily yield results for another. Currently, claims 1-36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected in each group consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Applicant is advised that in order for the reply to this requirement to be complete, it must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of the inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

27 November 2006
ARH

Ardin H. Marschel 12/9/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER